DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

d18986

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-60

June 25, 1998

Ms. Irene NMI Anderson
President and Owner
Technique Laboratories Corporation
4505 - 131st Avenue No.
Clearwater, Florida 34622

Dear Ms. Anderson:

This letter is written in reference to the marketing of various tanning accelerators by your firm, as determined by inspection of your firm by Investigator Christine M. Humphrey on October 20-23, 1997.

These product labels list "L-tyrosine", "acetyl tyrosine" or "unipertan" (which contains tyrosine) as ingredients and include such statements as "speed up the tanning process" (Hot Stuff 2000), "Heat Activated Red Hot Tan Booster" (Jamaica Me Crazy), "triple action tanning" (Jamaica Me Crazy Icy Tan Lotion with Melanin), "maximum tanning results in the shortest period of time" (Jamaica Me Crazy Magnifying Lotion), and "the most intense tanning experience ever" (Shazam Me Tan).

The Food and Drug Administration (FDA) states, on page 28293 of the Tentative Final Monograph for Sunscreen Drug Products for Over-the-Counter Human Use published in the May 12, 1993 Federal Register, that any product purporting to "accelerate the tanning process" or "stimulate the production of melanin" is claiming to affect the structure and function of the body and is, therefore, a drug [Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)]. We are not aware of any data demonstrating that tyrosine or its derivatives are effective in stimulating the production of melanin. We are also unaware of any drug with the composition of these articles marketed in the United States on or before December 4, 1975 for the uses intended for your products, nor are we aware that

drugs of these compositions are generally recognized as safe and effective for these labeled uses. Thus, any product containing tyrosine or its derivative and claiming to accelerate the tanning process is an unapproved new drug [Section 201(p) of the Act] and may not be legally marketed in the United States without an approved New Drug Application (Section 505).

These products are also misbranded in that the labeling declares ingredients not present in the products or fails to declare an ingredient which is present, and lacks the term "Manufactured For:" or "Distributed By:" preceding the distributor's name [Section 502(a)], fails to bear adequate directions for use for the conditions that are offered [Section 502(f)(1)], and are manufactured in a facility that is not registered with the FDA as a drug manufacturer nor have they filed drug listing information for their products [Section 502 (o)].

The referenced investigation also found that drug products manufactured by your firm are adulterated [Section 501(a)(2)(B)] since they are not manufactured in accordance with Current Good Manufacturing Practice (GMP) Regulations. For example:

> No documentation demonstrating testing of finished products,in-process materials or components; no stability tests are performed,nor do any labels bear expiration dates; no master records and incomplete batch records; no written procedures for component handling or testing, production and process control, testing methodology, packaging control, the distribution or recall of drug products, training of personnel, or cleaning/maintenance of equipment.

Further, two of your products, "Hot Stuff 2000" and "Jamaica Me Crazy Red Hot Tan Booster" are also adulterated because they contain the ingredient "capsicum", which is not declared on the label.

The violations cited in this letter are not necessarily intended to constitute an all-inclusive statement of all the violations that may exist for products marketed by your firm. You should review the conditions of all of your firm's products to assure that they are in compliance with the requirements of the Act. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct them may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action can not be completed within 15 working days, please state the reason for the delay and time within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida, Attn: Martin E. Katz, Compliance Officer, telephone no. (407) 475-4729.

Sincerely,

Douglas D. Tolen
Director, Florida District

cc: Mr. Anthony F. Cappola
Operations/General Manager
Technique Laboratories Corporation
4505 - 131st Avenue No.
Clearwater, Florida 34622